Analysis of Low Molecular Weight Silicones in Inamed Aesthetics Implant Gel and Shell by Gas Chromatography (GC) and Gas Chromatography-Mass Spectrometry (GC-MS)

REPORT OF ANALYSIS

The components of *Inamed Aesthetics McGhan Style 110, 510cc Implant* [redacted] were received on 20 January 2003. One jar was labeled *Silicone Gel* and one plastic bag contained the shell.

This study was undertaken to compare and confirm the identity of the silicone species in extracts using combined gas-chromatography-mass spectroscopy (GCMS) to confirm both by retention time and mass spectra. The solvents used were ethanol, hexane and dimethylsulfoxide (DMSO). Both the gel and the shell were separately extracted by each of the solvents and analyzed.

A second purpose for the study was to determine the effect of an evaporation step on the levels of the silicones. This was accomplished by comparing ethanol extracts with some of the same extracts that were subjected to concentration by evaporation and then reconstitution by dilution.

Table 4. Silicones in the Extracts

	Concentration (µg/g)			
Analyte	**Gel Extract**	**Gel Duplicate**	**Shell Extract**	**Shell Duplicate**
D5	11	12	6	5
D6	tr < 10	38	26	26
D7	tr < 10	27	18	19
D8	tr < 10	13	23	14
D9	tr < 10	12	10	8
MD7M	nd < 10	nd < 10	nd < 5	tr < 5
D10	13	26	19	16
D11	38	47	47	42
MD9M	nd < 10	10	6	nd < 5
D12	85	92	73	63
MD10M	23	19	7	6

tr = trace; nd = not detected (at the limits stated)

Table 5. Recovery after Evaporation/Reconstitution of the Gel

Analyte	**Reconstituted**	**Original**	**Ratio (%)**
D5	0.009	0.010	90
D6	0.034	0.044	77
D9	0.011	0.014	79
D12	0.098	0.096	102
MD10M	0.016	0.017	94
Duplicate			
D5	0.016	0.016	100
D6	0.058	0.055	105
D9	0.020	0.017	118
D12	0.151	0.139	109
MD10M	0.014	0.022	64

Table 6. Recovery after Evaporation/Reconstitution of the Shell

Analyte	Reconstituted	Original	Ratio (%)
D5	0.016	0.012	133
D6	0.073	0.064	114
D9	0.027	0.025	108
D12	0.216	0.208	104
MD10M	0.016	0.015	107
Duplicate			
D5	0.013	0.015	87
D6	0.079	0.078	101
D9	0.023	0.023	100
D12	0.192	0.200	96
MD10M	0.026	0.015	173

Use of evaporation to produce concentrated extracts does not appear to have a significant effect on silicone concentrations. The greatest variability from 100% recovery is due to the very low amounts of the analytes in the extracts.